

**510(k) Summary**

**MAY 28 2010**

**Medisim Ltd.**

**NIR Electrical Thermometer**

**510(k) Number K090386**

**Applicant's Name:**

Medisim Ltd.  
G.G. Communication Center  
Neve Ilan 90850, Israel  
Tel: 972-2-579-1921  
Fax: 972-2-579-1926

**Contact Person:**

Yevgenia Libster  
G.G. Communication Center  
Neve Ilan 90850, Israel  
Tel: 972-2-579-1921 ext. 826  
Fax: 972-2-579-1926

**Date Prepared:** January, 2009

**Trade Name of the device subject to this submission:**  
NIR thermometer

**Classification Name:**

Electronic Clinical Thermometer

**Classification:**

Clinical Electronic Thermometers are class II devices (product code 80 FLL) and are reviewed by the General Hospital Division and Personal Use Panel.

**Indication for Use:**

The NIR is non-sterile non-invasive infrared thermometer intended for the intermittent calculation of human body temperature of people of all ages for home and professional use.

**Statement of substantial equivalence:**

The **NIR** thermometer, which is the subject of this submission, is substantially equivalent to Exergen's TemporalScanner (**K011291**) which is the predicate device. Medisim's NIR and the aforementioned predicate device share the technology as well as the intended use. NIR as well as Exergen's TemporalScanner are ***intended for the intermittent measurement of human body temperature of people of all ages***. NIR device as well as the predicate device measure the temperature of a human by means of a thermopile infrared sensor/s transducer coupled with electronic signal amplification, conditioning, and display unit.

Both NIR and meet ASTM E1965-98 Standard for Infrared Thermometers for Intermittent Determination of Patient Temperature, to the extent that this standard applies to them.

For convenience, the various similarities and differences are summarized in the substantial equivalence comparison table.

	<b>NIR</b>	<b>The Predicate</b>
<b>Device Name</b>	NIR	TemporalScanner
<b>Manufacturer</b>	Medisim, Ltd.	Exergen corporation
<b>510(k) number</b>	K090386	K011291
<b>Thermometer type</b>	Infrared	Infrared
<b>Intended use(s)</b>	Measuring human body temperature	Measuring human body temperature
<b>Measurement Location</b>	Temple	Temple
<b>Clinical Setting</b>	Home Use	Home Use
<b>Labeling</b>	Instructions For Use are attached	User Manual is attached
<b>Sensor Type</b>	Thermopile	Thermopile
<b>Power requirements</b>	3.0V battery	9.0V battery
<b>Product Material</b>	Medical grade ABS	Medical grade ABS

	<b>NIR</b>	<b>The Predicate</b>
<b>Measured Temperature range</b>	22.0 °C to 40.0°C (71.6 °F to 104.0 °F)	15.5°C to 42.0°C (60.0 °F to 107.6 °F)
<b>Storage environment</b>	-20° C to 50° C (-4°F to 122°F)	Ambient temperature: -20.0°C to +50.0°C (-4.0 °F to 122.0 °F)
<b>Accuracy</b>	Below 0.3°C	±0.2°C/0.4°F between 37.0°C-39.0°C (98°F to 102 °F)

**NIR thermometer description:**

The device is built of one or more infrared thermopile sensors that is/are designed to measure a temperature above the artery on the skin.

Each of the sensor/s is mounted on a reflector which is used to reduce the sensor field of view. In order to minimize distance effects on the readouts the device is equipped with a distance measurement sensor. Each of the thermopile/s has its own thermistor which is used for calculating the self temperature of each sensor .

In addition there is another external thermistor which is used for measuring the ambient temperature and to assess the thermal condition of the thermal equilibrium of the device and to correct the result according to its value and the difference between the external sensor and the internal thermistors readout.

**Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence:**

The safe and effective performance of the device has been non-clinically and clinically established through comparative testing with market-cleared devices. NIR's safety has been checked and validated by Medisim's internal checks and Israeli Institute of standards. The clinical and bench tests demonstrated its accuracy and effectiveness.

NIR thermometer complies with additional **voluntary** standards:

IEC60601-1 (1995) General safety requirements for medical devices

IEC 60825-9 (1999) Safety of laser products

## ISO 14971 (2007) Risk analysis for medical device

### **Conclusion:**

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the **NIR** Electrical Thermometer is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Ms. Yevgenia Libster  
Regulatory Manager  
Medisim, Limited  
G.G. Communications Center  
Neve Ilan  
Israel 90850

MAY 28 2010

Re: K090386  
Trade/Device Name: Non-Invasive Infrared (NIR) Thermometer  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electric Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: April 26, 2010  
Received: May 6, 2010

Dear Ms. Libster:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

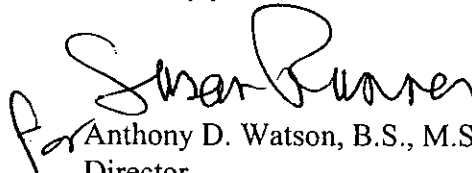
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson".

Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number:

Device Name:

NIR

Indications for Use:

The NIR is non-sterile non-invasive infrared thermometer  
intended for the intermittent calculation of human body  
temperature of people of all ages for home and professional use.

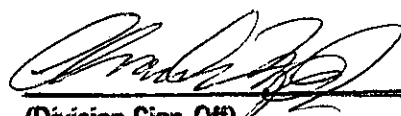
Contra Indications: NA

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use ✓  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
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(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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